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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Aujeszky's disease

EFSA Panel on Animal Health and Welfare (AHAW)

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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): Aujeszky's disease

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Abstract

Aujeszky's disease has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of Aujeszky's disease to be listed, Article 9 for the categorisation of Aujeszky's disease according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to Aujeszky's disease. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, Aujeszky's disease can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. The disease would comply with the criteria as in sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1). The animal species to be listed for Aujeszky's disease according to Article 8(3) criteria are mainly the species of the family of Suidae as susceptible species, although almost all mammals can be infected, and *Sus scrofa* as reservoir species.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and Article 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

1.1.1. Interpretation of the Terms of Reference

The interpretation of the ToR is as in section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on Aujeszky's disease according to the criteria of the AHL articles as follows:

- Article 7: Aujeszky's disease profile and impacts;
- Article 5: eligibility of Aujeszky's disease to be listed;
- Article 9: categorisation of Aujeszky's disease according to disease prevention and control rules as in Annex IV;
- Article 8: list of animal species related to Aujeszky's disease.

2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of Aujeszky's disease according to the Article 7 criteria of the AHL and related parameters (see table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) Disease Profile

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

The primary and only natural host¹ of Aujeszky's disease (AD) is the pig (*Sus scrofa*), including wild boar or feral pigs and all genera of the family of Suidae. There are very few reports of detection of ADV in peccaries (Tayassuidae), the significance in this family is difficult to determine due to the absence of relevant pathological studies (De Castro et al., 2014). However, a large number of other animal species can be infected naturally or experimentally by the Aujeszky's disease virus (ADV): cattle, sheep, goats, dogs, cats, terrestrial wild carnivores and wild mice. Nearly all other mammals are also thought to be susceptible to the infection, except higher primates, but as dead end hosts (Spickler, 2017). It is difficult to infect horses and birds; large virus doses are necessary and they must be injected either intracerebrally, subcutaneously or intramuscularly (Mettenleiter et al., 2012). Higher primates, including humans, are considered non susceptible to the virus, in spite some clinical cases reported in humans (see Section 3.1.1.3). Susceptibility to infection depends on several factors

¹ Natural hosts are able to survive a productive pseudorabies infection dependent on the age of the animal and the virulence of the virus.

including the virulence of the virus strain, the exposure dose, the route of exposure, and the age (piglets are highly susceptible compared to adult pigs).

Reservoir animal species

The pig (*S. scrofa*) (including wild boar or feral pigs) is the only species that serves as the reservoir host (Mettenleiter et al., 2012).

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/incidence

In a susceptible porcine population, the within-herd prevalence is variable depending on the structure of the herd, its health management, the density of the pigs, the distance between the facilities and the biosecurity measures applied by the farmer. In farms with few animals and no vaccination, serological testing demonstrated a prevalence of the infection below 20%; whereas in bigger farms, mainly in breeding and finishing herds, generally the prevalence has been shown to be much higher and can reach 60% or even 100% (Vannier, 1989). In a more recent survey conducted in Spanish farms without vaccine interferences, the percentage of seropositive herds was 55% (39–70, 95% CI) in sows and 25% (14–41, 95% CI) in fatteners, while the median within-herd seroprevalence was 37% (9–87, 95th percentiles) and 100% (7–100, 95th percentiles) in sows and fatteners, respectively (López-Soria et al., 2009).

Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

In pigs, morbidity is dependent on the age of the animal. It is not always possible to associate the within-herd prevalence with case-morbidity, since the clinical expression of the infection in a given herd depends on multiple factors, and the case-morbidity can be highly variable. In suckling pigs, the case-morbidity is 100% in most cases. In breeders, the case-morbidity is generally high, but the clinical expression of the infection can be limited to hyperthermia and anorexia; the rate of abortion is variable depending on the stage of gestation. In fattening pigs, the case-morbidity might be linked also to the presence of additional infections; for example, in herds with a high sanitary standard, the clinical expression of the ADV-infection can be very mild, whereas in herds with the presence of other infectious agents, such as *Mycoplasma*, *Actinobacillus*, Porcine Reproductive and Respiratory Syndrome Virus, or Swine Influenza, the frequency of respiratory disorders after the infection by the ADV can be very high (Vannier, 1987a). In other ADV-infected species the case-morbidity is always 100%.

Mortality

Parameter 3 – Case-fatality rate

In pigs, the case-fatality is strongly dependent on age. Generally, 100% of suckling 15 days old piglets will die after an ADV infection. In 3 weeks to 1-month-old piglets, the case-fatality decreases to 50%. After weaning as well as in fattening units, the mortality is low, although depending on the sanitary standard of the herd; if secondary infections are introduced after the ADV infection (see above), the mortality can increase considerably, reaching 10% (Pol and Le Potier, 2011).

In other species, such as cattle, sheep, goats, cats and dogs, clinical pruritus and encephalitis characterise the uniformly and systematic fatal infections, i.e. the case fatality is always 100%. It is important to realise that before the 1970s, AD was reported only for cases of mortality in cattle or companion animals, such as dogs and cats, whereas the infection in the porcine reservoir population was not recognised.

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

Since 1914, there are several anecdotal reports of AD in humans. Between 1983 and 1986, three suspected human cases of AD were identified in Europe. Each of these patients had a history of having direct contact with cats and other domestic animals. Researchers followed up on the cases and identified ADV antibodies through neutralisation and immunoprecipitation assays, 5–15 months after onset of clinical illness. However, later serological studies were unable to detect ADV antibodies in occupationally exposed populations (Mravak et al., 1987; Skinner et al., 2001). So, these reports are

not conclusive; it is generally accepted and has been demonstrated even by self-inoculation that humans are resistant to natural AD infection (Mettenleiter et al., 2012).

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

This is not applicable as AD is a viral disease and there is no treatment available.

3.1.1.5. Article 7(a)(v) The persistence of the disease in an animal population or the environment

Animal population

After an experimental challenge in pigs, the virus can be isolated from nasal swabs up to 12 days, with virus titres between 10^3 and 10^7 50% Tissue Culture Infective Dose (TCID₅₀) per swab (Vannier et al., 1991). In oropharyngeal swabs, the virus can be detected up to 25 days. Virus is found in vaginal secretions and foreskin secretions (ejaculate) for up to 12 days and for 2–3 days in milk; transplacental transmission leads to considerable virus shedding by the sow during abortion and birth of dead born piglets. Virus is occasionally shed in urine and has been detected in rectal swabs, but not in faeces, for up to 10 days (Mettenleiter et al., 2012).

Latency is defined as a condition in which viral genomic DNA persists extra-chromosomally, but infectious virus is not produced. A number of studies have suggested that most, if not all, pigs initially exposed to ADV can become latently infected carriers. In consequence, virus can be reactivated and excreted several months or years after the initial infection (Smid et al., 1994). Reactivation can occur due to stress (transport, handling, temperature, etc.) or hormonal imbalance (gestation, farrowing).

The other susceptible species do not contribute to persistence or latency of the virus, as the fatal outcome is systematic and occurs few days after the infection.

Environment

Parameter 4 – Length of survival of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low temperature)

ADV is stable under various pH and temperature conditions and is considered resistant in the environment. The virus survives on hay for 30 days in summer and 46 days in winter. It is stable between pH 4 and 12, and even at pH values of 2.0 and 13.5, it takes 2–4 h before the virus is completely inactivated. ADV is relatively resistant to heat. It is inactivated at 60°C in 30–60 min, at 80°C in 3 min and at 100°C within 1 min (Kunev, 1978). Under laboratory conditions, it stays infectious at 25°C for about 6 weeks, at 15°C for about 9 weeks and at 4°C for about 20 weeks (Davies and Beran, 1981). In slurry, the virus is thought to remain infectious for about 2 months in winter and for about 1 month in summer. At high virus doses ($10^{6.5}$ TCID₅₀/mL), infectious virus can still be detected after 27 weeks at 4°C and 15 weeks at 23°C. In aerated slurry, at pH 9.6 and 44°C, infectivity disappeared in 8–21 days. In soil, infectious virus was recovered for 5–6 weeks. Virus dried on sacks and wood persisted for about 10 days in summer and 15 days in winter (Mettenleiter et al., 2012).

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

The virus is spread primarily by direct contact between pigs. Close direct contact is the main route of transmission of the virus between pigs or wild boar. The mucosae of the nasal and oral cavities are the main entry points. The virus can also spread via colostrum to suckling piglets (Beran, 1991). Transmission among pigs can also occur during breeding from exposure to contaminated vaginal mucosae or semen. Sows are often infected during mating or artificial insemination by infected boars or infected semen. In the back-yard sector, mainly in the past, boars were transported from farm to farm for mating ('rolling/travelling boars') and, when they were infected, they could contaminate numerous free holdings (Vannier, 1987a). Under certain climatic circumstances (high virus load in the air, ventilation, etc.), ADV can be disseminated by the movement of air within buildings or outside (Vannier, 1989). Cows were often infected and died, when reared close to infected pigs or outdoors close to the exhaust of air coming from the pens of heavily infected pigs. Offal of pigs and products containing pig offal (such as head as well as thoracic and abdominal

viscera) can represent a further transmission route for pigs and other species, if used in feed (see Section 3.1.4.7).

The relative importance of the different transmission routes depends on the density of pig herds. In areas with a low density of pig herds, transmission occurs mostly by introduction of infected gilts or boars, and infected semen used for artificial insemination. Finishing herds are often contaminated by the introduction of piglets from infected farrowing units (Vannier, 1987b). In areas with a high density of pig herds (≥ 0.8 herds per ha), different studies (Donaldson et al., 1983; Christensen et al., 1990) showed that the virus can be transmitted by air (up to 70 km), and Danish pig farms were shown to be contaminated through airborne virus from infected German pig farms. In areas with a high density of pig farms, mainly consisting of farrow-to-finish herds and finishing herds, the virus burden can be very high when several pig farms are infected at the same time and the virus can spread from farms to farms very quickly.

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

A study conducted in 17 herds quarantined for ADV spread to determine the incidence of ADV within enzootically infected herds detected ADV-infected animals in seven of eight herds that had more than 400 sows and in two of nine herds that had less than 400 sows. Sample size was established to detect spread if it was occurring in at least 20% and 22% of 15 and two susceptible herds, respectively, on annual basis. Annual incidence ranged from 61% to 4.7% (Duffy et al., 1991).

Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

R_0 values of 10 and 23 have been suggested in vaccination studies (De Jong and Kimman, 1994; Bouma et al., 1997).

The speed of transmission of ADV depends on the local structure of the production; in areas with a high density of infected and susceptible finishing pigs, and with movements of potentially infected piglets, the combination of massive aerial excretion of the virus with mixing of animals of different origins and health status creates favourable conditions for rapid spread of the infection among herds. In contrast, in areas with a relative low number of pig herds, such as Loire-Atlantique (247 herds within 6,815 km²) in 1983 and Aquitaine, in the south-west of France, with 5,200 herds (within 41,310 km²) and with 75,000 sows of which 3,900 were infected, the spread of ADV was relatively limited and slow allowing the implementation of sanitary measures with a very limited vaccination coverage (Vannier et al., 1997).

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in EU

The disease is still present in 13 Member States (MS) and consequently in a significant part of the Union territory. The list of Member States or regions thereof with an approved eradication programme or with the recognised AD-free status, and having the related additional guarantees granted for intra Union trade, are listed in Annexes I and II to Commission Decision 2008/185/EC.² The situation in 2015 is presented in Figure 1 as in point 2.5 of the annual report for bovine and swine diseases: http://ec.europa.eu/food/sites/food/files/animals/docs/la_bovine_final_report_2015.pdf. Nevertheless, in many of the countries, the infection, if present, is endemic in the wild boar population; ADV has been isolated from these animals in Austria, France, Germany, Hungary, Italy, Slovakia and Spain (Muller et al., 2010). The occurrence of the virus in the wild boar population seems to be variable according to regions and seems to be associated with the density.

² Commission Decision of 21 February 2008 on additional guarantees in intra-Community trade of pigs relating to Aujeszky's disease and criteria to provide information on this disease. OJ L 59, 4.3.2008, p. 19–30.

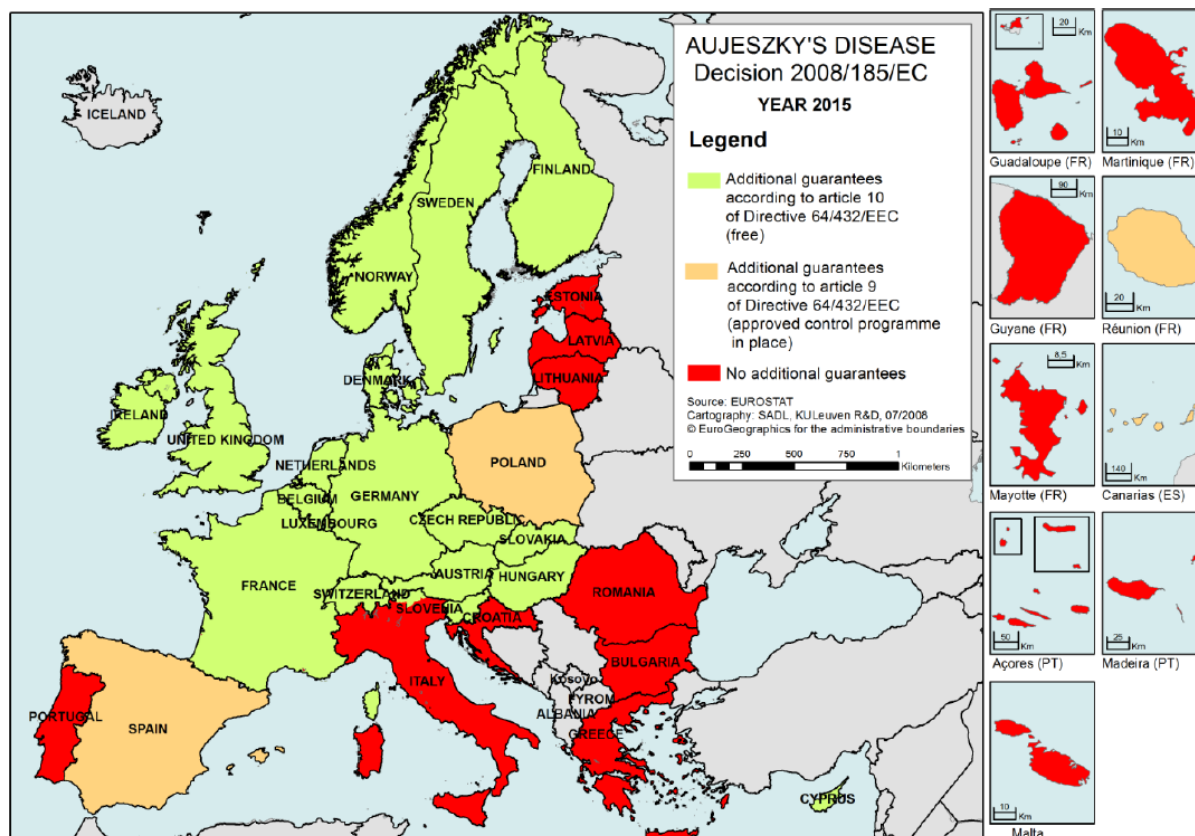


Figure 1: Map of EU Member States, Norway and Switzerland free of Aujeszky's disease (in green), or where the disease is still present (in orange for countries with an approved control programme in place, in red for other countries) (source: http://ec.europa.eu/food/sites/food/files/animals/docs/la_bovine_final_report_2015.pdf)

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

In all MSs where AD is present, the epidemiological situation is variable and the infection can be considered as endemic.

Risk of introduction

The risk of introduction of AD is mainly linked to the routes of transmission of the ADV. The highest risk is associated with the trade of live infected piglets, infected breeders (sows and boars), and infected semen. The movement of infected wild boar across borders can be another possible route of spread and introduction of the virus into free countries. Similarly the spill-back from still infected wild boar (present and infected in most nowadays free countries) to pigs, particularly open-air or free-range raised ones can be a further spread or introduction route.

The number of animals moved is highly variable from one MS to another.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

Parameter 1 – Existence of diagnostic tools

The diagnosis of AD can be confirmed by isolating the virus from the oropharyngeal fluid, nasal fluid (swabs) or tonsil swabs from living pigs, or from samples from dead pigs or following the presentation of clinical signs, such as encephalitis in herbivores or carnivores. For post-mortem isolation of ADV, samples of brain, tonsil and lung are the preferred specimens. In cattle, infection is usually characterised by a pruritus, in which case a sample of the corresponding section of the spinal cord may be required in order to isolate the virus. In latently infected pigs, the trigeminal ganglion is the most consistent site for virus isolation, although latent virus is usually non-infective unless reactivated, making it difficult to recover in culture.

The polymerase chain reaction (PCR) can be used to identify ADV genomes in secretions or organ samples. Many individual laboratories have established effective protocols (OIE, 2012).

Virus neutralisation (VN) has been recognised as the reference method for serology; the VN test is a prescribed test for the international trade (OIE, 2012).

For general diagnostic purposes, it has been widely replaced by the enzyme-linked immunosorbent assay (ELISA) because of its suitability for large-scale testing. The tests can be performed on a variety of matrices (e.g. serum, whole blood, milk, muscular exudates, including these matrices collected on filter paper), but the preferred matrix is serum (Pol and Le Potier, 2011). ELISA kits, which are available commercially, use indirect or competitive techniques for detecting antibodies. They differ in their mode of preparation of antigen, conjugate or substrate, in the period of incubation and in the interpretation of the results. Their general advantage is that they enable the rapid processing of large numbers of samples, they may be automated and the results analysed by computer (OIE, 2012).

Serological tests are carried out only in pigs, as other animals (herbivores and carnivores) die too quickly to produce antibodies. In free areas where pigs are not vaccinated, an active epidemiological survey can be carried out using ELISA gB kits. As antibodies can be detected between 7 and 10 days post-infection, this serological tool can also be used in case of an outbreak suspicion to confirm the infection of pigs. In areas where pigs are vaccinated with gE-deleted vaccines, the ELISA gE kits allow the differentiation between infected and vaccinated pigs (DIVA), but to assess the level of immunity induced by vaccination, gB ELISA kits or viral neutralisation should be used. The sensitivity of ELISA is generally superior to that of VN test using 1-h neutralisation without complement. Some weak positive sera are more readily detected by VN tests using 24-h neutralisation, while others are more readily detectable by ELISA.

A latex agglutination test has also been developed and can be used for screening for antibodies.

Control tools

Parameter 1 – Existence of control tools

All the tools necessary to control and eradicate the disease are available and have been implemented in the past with satisfying results (see Section 3.1.4).

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

See Section 3.1.1.7.

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation (milk, growth, semen, meat, etc.)

There are limited studies about the direct cost of AD. A precise estimation has been done in two unvaccinated farrow-to-finish herds (80 sows) taking into account the mortality of piglets, sows and fattening pigs, as well as the rate of abortion (Godet and Vannier, 1983). The increase of the feed consumption index was also estimated. In the two respective herds, 132 and 131 piglets died, 3 sows died in one herd, 5 and 7, respectively, aborted, 2 and 3 fattening pigs died. The feed consumption index increased by 0.2 in each herd. The cost was calculated in each herd taking into account the antibiotic additives distributed to cure respiratory disorders and the secondary bacterial infections. The total cost was 15,051 € (188 € per sow) in one herd and 18,498 € (230 € per sow) in the other one. These estimates incorporate an inflation of 1% per year from 1983 to now.

The losses, however, can be variable from herd to herd. Especially, in the finishing units, indirect losses related to a decrease in growth measured by the mean daily growth (MDG) value are strongly dependent on the herd health status. Under experimental conditions, when the conditions of challenge are strictly identical, the only variation may be due to the original health status of the pigs, as described in the following.

Among 41 pigs scattered in seven batches, after challenge with the strain 75V19 at 14–20 weeks of age and a weight between 70 and 80 kg, the MDG before challenge varied from 767 to 1,015 g; the

total loss of weight after challenge varied from 7.1 to 15.8 kg; the MDG during 7 days post-challenge varied from 821 to 2,000 g and during 21 days post-challenge, the MDG varied from 416 to 481 g. The time to recover the weight they had before challenge was from 13 days to more than 36 days. None to five animals died in the different batches (Vannier, 1987a). In these assays, there were specific pathogen-free (SPF) pigs, pigs coming from herds with no respiratory disorders and from conventional herds with chronically respiratory disorders. The differences of performances after challenge can be explained by the importance of respiratory lesions due to secondary bacterial lung infections (Vannier, 1987a). Indeed, when SPF pigs are experimentally infected, the pneumonia lesions induced by the ADV appear in few days after challenge and evolve quickly to cicatrization. For pigs coming from herds with chronic respiratory disorders, pneumonic lesions are much more extensive, with purulent exudate and lesions of pleurisy, pericarditis and peritonitis.

In a study in US conducted in 1990 in a commercial swine herd, preweaning mortality increased twofold, and subsequently, the number of pigs weaned per litter decreased by 19% ($p < 0.005$) during the 5-week epizootic. Also, the number of pigs born alive decreased by 6% during the epizootic. No significant differences in production were observed between the 6-month periods before and after the epizootic (Parsons et al., 1990).

A more recent Japanese study investigating the effect of ADV infection on productivity in farrow-to-finish herds, found a significant higher post-weaning mortality in ADV-positive herds (6.84%, 2.29 SD) compared to negative herds (4.73%, 1.78 SD) and lower marketed pigs per sow (20.1, 2.06 SD), litters per mated females per year (2.28, 0.15 SD) and farrowing proportion (80.7%, 6.39 SD) than negative herds (21.7, 2.69 SD; 2.35, 0.12 SD; 85.1%, 7.40 SD, respectively) (Yamane et al., 2015). As targeted herds volunteered to be part of this study, the authors specified that this selection bias could have resulted in the inclusion of herds with higher levels of animal hygiene and those with motivated owners.

More global studies have been carried out, but it is difficult to compare the different values of direct and indirect costs induced by AD. In Ohio (USA), estimates ranging from \$21 million to nearly \$33 million annually have been proposed for the annual loss experienced by the US swine industry due to infection with ADV (Bech- Nielsen et al., 1995). An earlier study (Bech- Nielsen et al., 1992) investigated the effect of pseudorabies in swine farming on both production and economic values. The study reported an overall loss of 99,700 \$ from the beginning of the epizootic to the complete eradication. The major economic loss was related to suckling pig mortality, which accounted for the 76.5% of the total loss and nursery pig mortality (12.6% of the total loss). Culling and death of sows accounted for 9.4% of the total losses that occurred from 6 months after the epizootic until eradication. The remaining 1.2% of the total loss in the same was represented by marketed hog deaths.

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

Humans are resistant to natural AD infection, thus there is no impact on human health (see section 3.1.1.3).

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

The consequences on animal welfare are related to the clinical signs induced by the virus and to the lesions due to the virus favouring also secondary bacterial infections, complicating the course of the initial infection. In piglets, the lesions of encephalitis are expressed as severe and painful clinical signs such as paddling, opisthotonos, convulsions, etc., and are always fatal. In other species than pigs, the lesions of encephalitis are often expressed as a severe pruritus leading the infected animals to self-mutilation, in attempt to alleviate the intense pruritus and the pain. Again, death is inevitable. The old name of AD is 'mad itch', which expresses very well the dramatic negative impact of the infection on animal welfare, as well as the name 'pseudorabies', some AD clinical signs being very similar to the ones of rabies.

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

AD can cause significant mortality in wild boar (Gortázar et al., 2002). Foxes and other meat-eating wildlife species can be infected and killed by eating dead infected piglets and aborted fetuses.

However, it is very difficult to obtain precise statistics in these cases, although there are reports confirming cases in several endangered carnivores, most recently an Iberian lynx (Masot et al., 2017).

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

Wild boar is a potential reservoir and source of infection for domestic pigs, especially in those countries where AD eradication programs have been successfully implemented. In Europe, ADV is present in wild boar in many countries, such as France, Germany, Spain, Italy, Slovenia, Croatia and the Czech Republic (Mettenleiter et al., 2012). The seroprevalences in these populations range from 4% to 60% at the regional and national levels; these differences seem to be related to the density of the wild boar population and to the frequency of contacts between these animals. This endemic infection of wild boar is revealed by serological investigations, while the occurrence of deaths among hunting dogs can be examined with viral isolation or detection of ADV sequences from the brain of these dogs. The number of infected hunting dogs varies from region to region, depending on the habits of hunters to distribute wild boar viscera to their dogs (Pol and Le Potier, 2011). Although AD in wild boar generally has not impacted the AD-free status of domestic pigs, infected wild boar populations represent a constant danger for reintroduction of ADV into free regions and countries.

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

ADV is not included in any of the lists of agents to be potentially used in bioterrorism.

3.1.4. Article 7(d) The feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Availability

Currently, there is no European Union (EU) Reference Laboratory for AD. National institutes responsible for checking the quality of ELISA methods in each MS and for producing and standardising national reference sera according to the Community reference sera are listed in Annex III to Commission Decision 2008/185/EC.

Effectiveness

ELISAs used in Europe are accurate in comparison to the blocking and indirect ELISAs, with a relative sensitivity of 95.12% and 99.37%, respectively, and a relative specificity of 92.0% and 93.5%, respectively (Wongwatcharadumrong and Moreno-Lopez, 1990). However, papers reporting precise sensitivity or specificity estimates are rare. Most of the tests used currently probably have values up to 96–99% sensitivity and specificity (Le Potier, 2016).

Feasibility

ELISA kits are used on sera (tested individually or pooled in batches of five) and for the gB kits, filter papers are used to collect blood; the analysis is performed from the elution obtained with an appropriate buffer. A reference serum-neutralisation test is less frequently used on a routine basis.

Tonsils, brain, lungs, and lymph nodes are generally the matrices used to isolate the virus or to detect ADV sequences.

3.1.4.2. Article 7(d)(ii) Vaccination

Availability

There are inactivated and live attenuated vaccines. In countries with infected pigs, where eradication of AD is planned, the gene-deleted marker vaccines are the vaccines of choice. The epidemiological and economical effectiveness of this methodology for regional eradication was documented in 1991–1994 by an EU-supported project, involving regions in Denmark, Germany and parts of the Netherlands. The vaccination/test-and-removal programmes, which were carried out in northern Germany and southern parts of the Netherlands, were the first ever area-wide attempts to eradicate the AD virus from large populations of endemically infected swine herds with the use of gene-deleted vaccines (Willeberg et al., 1996).

As most of the European countries eradicated the infection, it is possible that, in case of a crisis at EU level, it will be difficult to obtain enough vaccine doses from the manufacturers to protect the endangered population.

Effectiveness

The vaccines are efficient in providing complete protection for young piglets through passive immunity by vaccinating the dams before farrowing. The vaccines prevent abortion in most cases. However, in exceptional circumstances, abortion can occur in herds where vaccination with an inactivated vaccine has been performed in sows. Generally, this occurs when the 'infectious pressure' is very high, the wild AD virus is spreading in a herd with vaccinated sows and unvaccinated fattening pigs. The virus can reach the fetus despite a strong humoral immunity (Dieuzy et al., 1987).

In fattening pigs, the active immunity induced by vaccination will be more or less efficient depending on several factors, such as the age of (time since) vaccination, as the passive antibodies may interfere with the development of an active immunity after vaccination, the number of injections at the beginning of the fattening period, the type of vaccines (inactivated or live attenuated), the health status of pigs before vaccination, and infections with or without chronic respiratory disorders. The clinical protection of the fattening pigs can be measured by objective criteria such as index DG, which is the difference in mean relative daily weight gain (MRDG) during the 7 days post-challenge period between vaccinated and control groups (Vannier et al., 1995). Such criteria are used by the European Pharmacopeia to provide the rules for marketing authorisation (European Pharmacopoeia, 2013). When fattening pigs are immunised, the difference of the MRDG values between the control and vaccinated groups 7 days after challenge should not be less than 1.5 kg, with no vaccinated pigs dying after challenge. To measure the clinical protection induced by the passive immunity from vaccinating the dams, their 6–10 days old piglets are challenged: 100% of the control piglets should die after challenge and 80% or more of the piglets from the vaccinated sows should survive to the challenge.

However, vaccination of pigs does not prevent viral shedding and latency. Vaccination shortens the period of viral excretion after infection and decreases the quantity of virus excreted.

Assays showed that a double vaccination of seronegative pigs reduces transmission of ADV among vaccinated pigs compared to the transmission among the unvaccinated pigs (De Jong and Kimman, 1994). The R_0 was reduced from 10 to 0.5. However, when a single vaccination was performed at 10 weeks of age in pigs with maternal antibodies, R_0 was equal to 23, whereas, when a double vaccination was carried out with presence of maternal antibodies at 10 and 14 weeks of age, the R_0 decreased to 0.6 (Bouma et al., 1997). No vaccines can prevent latent infection and subsequent reactivation and shedding of virulent field virus (Mettenleiter et al., 2012).

Parameter 3 – Duration of protection

Passive protection: The duration of the persistence of the passive antibodies depends on numerous factors: the number of vaccine injections given to the dams – also related to the age of the sows – the type of vaccine used, the quantity of colostrum taken in by the neonatal piglet, its rank in the litter, the temperature of the environment of the piglet at the moment of birth. With the most efficient vaccines given to the sows, passive antibodies can be detected in the serum of 17 weeks old pigs (Vannier, 1985). However, in most cases, passive antibodies are detected in the serum of fattening pigs until 12–14 weeks of age.

Active protection: Whatever the type of vaccine (live-attenuated or inactivated), the active immunity does not provide a good protection beyond 6 months after vaccination; therefore, booster injections should be carried out every 6 months.

Feasibility

Most vaccines are administered by the intramuscular route. This is done easily under practical conditions, when the pigs are reared in closed buildings. The implementation of a systematic vaccination programme is more difficult when pigs are reared on free range, as occurs in some regions within the EU, such as Corsica and Sardinia.

To prevent local reaction, few vaccines have got a marketing authorisation for the intradermal route (Vannier and Cariolet, 1989).

3.1.4.3. Article 7(d)(iii) Medical treatments

This is not applicable (see Section 3.1.1.4).

3.1.4.4. Article 7(d)(iv) Biosecurity measures

In most cases, the classical biosecurity measures (control of health status of purchased pigs, quarantine, fencing, shower or change of clothes for staff and visitors, water-bath for boots and truck wheels, etc.) are efficient to prevent the introduction of the virus into a herd. These measures are currently applied in most herds in countries with a developed porcine production and industrial pig farms. Nevertheless, in some MSs, pig farms with no protection and no implementation of biosecurity measures may still be found.

In areas with a high density of infected pig herds, airborne transmission of the virus is possible (see above); accordingly, classical biosecurity measures are inefficient in those cases. To prevent the introduction of the virus into nucleus herds or semen collection centres, filtration of the air entering into the pig buildings was implemented in these high-level health-status herds (Dutertre et al., 1995). Depending on the level of risk, F9 filtration (99% of efficiency on particles $\geq 1 \mu\text{m}$) or H12 filtration (99.5% efficient on particles whatever their size) was implemented in those herds.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products

In most countries, especially when the initial prevalence of the infection is variable from region to region or relatively high (see above), control and eradication programmes were implemented following different steps. Indeed, a programme of control against AD can be successful only if a comprehensive set of measures is carried out.

3.1.4.6. Article 7(d)(vi) Killing of animals

In AD eradication programmes, depending on the epidemiological situations, three different specific measures were carried out: total slaughter, partial slaughter (part of the herd) after a test-and-culling procedure or a systematic DIVA vaccination programme with backup serological examinations in fattening pigs and breeders long enough to ensure that the herds do not pose any epidemiological risk to the neighbourhood; in those herds, when the regular culling of sows inside each herd allowed an elimination of infected breeders, a test-and-slaughter procedure could be implemented for breeders to accelerate the cleaning of the herds. Infected breeders were then sent to slaughter.

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

There is no restriction on the consumption of carcasses, as ADV is not zoonotic. Moreover, the virus is rarely isolated from the blood and the meat. Nevertheless, offal (head as well as thoracic and abdominal viscera) of pigs and products containing pig offal represent an epidemiological risk for pigs and other species, if used in feed. For that reason, those products cannot be used or introduced in free regions or countries from provisionally free countries or zones or from infected countries or zones, if they do not come from an officially free establishment or if they have not been processed to ensure the destruction of the AD virus (OIE, 2016).

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

It is often thought that sanitary measures are much more costly than vaccination preventive measures. The AD eradication programmes costs are proving the opposite. However, very few studies have been done on that subject. Precise costs were established in French regions with sanitary programmes including total or partial slaughter of herds and, in exceptional cases, vaccination of limited herds with test-and-slaughter of infected sows and boar. For example, in Loire-Atlantique, which included 247 herds, the programme began in 1983. Over 3 years, the costs of the eradication programme approximated 180,000 €, including everything: blood sampling, laboratory analyses, vaccines, compensation, mortality, staff and travel expenses. The programme included 10,000 sows, making the cost per sow per year of 6 €. Farmers paid a levy of 4.31 € per sow per year. Local or regional authorities covered the remaining costs. This calculation took into account an inflation of 1% per year. The veterinary authorities paid only part of the staff and supplied the kits for the serological tests. In the region of Aquitaine (1984), where vaccination was prohibited after 2 years of campaign, 80,000 blood samples were drawn from 5,200 herds. Out of these samples, 3,900 sows were infected and 4,200 have been slaughtered in the first stage of the eradication campaign. Here, the total cost had been 1,800,000 € for 75,000 sows in a period of 4 years that means 24 € per sow or 6 € again

per sow per year. The levy paid by the farmers for the first and second year was around 2 € per sow per year (a little more the next 2 years), the remainder was paid by local, regional and national authorities (Vannier et al., 1997).

The costs were much higher in regions with a vaccination programme. Indeed, in Brittany, in a first step, the pig producers decided to implement only a systematic vaccination programme without any other general or specific measures. From 1987 to 1992, during 5 years, in each herd, sows, boar and fattening pigs were systematically vaccinated. At the end of this period, the campaign was a failure as the prevalence of the infection in the region was the same as before the programme implementation. So, in 1994, the producers accepted to change of strategy: to maintain a systematic vaccination, but associated to other general and specific measures as described before. Therefore, the cost of the programme had to include the cost of vaccination in each animal (breeders and fattening pigs) every 6 months cumulated on the number of years to reach the eradication plus the cost of blood sampling and testing and the costs related to the anticipated culling of infected breeders. In regions with sanitary programmes, the eradication can be reached in 3–4 years, whereas, in regions with medical prophylaxis, eradication is rarely reached before 10–15 years or more.

According to Willeberg et al. (1996), a computerised economical model to estimate the effects of ADV infection at the herd and area levels has been developed as part of the EU project on AD vaccination in Germany and the Netherlands, 1991–1994. The analytical structure consisted of a basic epidemiological model linked to an economic estimation framework. The economic model predictions allow priorities to be given to alternative control strategies. Mass vaccination of all pigs in regions with endemically infected herds followed by test-and-removal of seropositive animals is the most cost-effective way to control the spread of ADV within the swine population. Other possible control strategies, such as intensive vaccination or complete test-and-removal, all had higher overall costs, either because of the less efficient production or because of the high costs of straight test-and-removal.

As some regions or countries eradicated AD, indirect costs are related to the limitations of trade of live animals between infected regions or countries and officially-free ones. As example, the estimated cost of AD per year in the US was over 30,000,000 \$ (APHIS, 1999).

A probabilistic risk assessment and cost-effectiveness analysis using Monte Carlo simulation was developed for the Guijuelo region in Spain to assess the most safety strategy for moving the animals and avoiding the risk of introducing ADV-infected pigs in free or low-prevalence areas and the related cost of the strategy (Mártinez-López et al., 2009). The overall cost of the AD programme for Guijuelo was 649,398 € per year, due to the costs of the tests (885 €), of the veterinarians (631,071 €) and of vaccination (16,609 €); the reference strategy consisted in testing the animals 15 and 45–170 days prior to the movement for breeding pigs and fattening pigs, respectively, using a sample size sufficient to detect a 2% prevalence with 95% CI in breeding farms and a 5% prevalence with 95% CI in fattening farms. According to the authors, the risk of ADV introduction could be reduced by 89% testing fattening farms 15 days prior to animal movement without additional cost, and by 99% increasing the sample size to detect a 1% seroprevalence, although the cost would increase by 91%.

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

To eradicate AD, stamping out in the farm of the infected animals was never carried out, thus, there is no problem of social acceptance of the eradication programmes.

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

There is no welfare impact beyond normal practice for the control measures adopted in domestic pigs, as the infected animals are sent to slaughterhouses.

Parameter 2 – Wildlife depopulation as control measure

There are no possible control measures of AD on wildlife, except to set up fences to prevent the mating of sows in oestrus by wild boar. These measures have no real impact on the welfare of wildlife.

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Other types of impact on environmental compartments such as soil, water, feed and manure linked to the use and potential residuals of biocides or medical drugs is not relevant, since no medical treatment is applied.

Biodiversity

Parameter 2 – Mortality in wild species

The impact that AD may have on biodiversity can be linked to the potentially increased mortality in meat-eating wildlife including endangered species.

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about AD (Table 1). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was 11. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 1: Outcome of the expert judgement on the Article 5 criteria for Aujeszky's disease

Criteria to be met by the disease: According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		Final outcome
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at point A(i)-A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	Y
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	Y
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	NC

Colour code: green = consensus (Yes/No); yellow = no consensus (NC); red = not applicable (na), i.e. insufficient evidence or not relevant to judge.

3.2.1. Non-consensus questions

This section displays the assessment related to each criterion of Article 5 where no consensus was achieved in form of tables (Table 2). The proportion of Y, N or na answers are reported, followed by the list of different supporting views for each answer.

Table 2: Outcome of the expert judgement related to criterion 5 B(v)

Question	Final outcome	Response		
		Y (%)	N (%)	na (%)
B(v) Disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	NC	55	45	0

NC: non-consensus; Number of judges: 11.

Reasoning supporting the judgement

Supporting Yes:

- ADV can cause deaths in endangered carnivores, e.g. bear, lynx (Masot et al., 2017). Few deaths in already rare animal species may have an impact on the biodiversity, at least in local situations.

Supporting No:

- ADV currently still exists in wildlife populations (including wild boar) in many MSs, even in those that have eradicated ADV in domestic pigs, without any apparent serious negative impact on the environment or biodiversity.

3.2.2. Outcome of the assessment of Aujeszky's disease according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 1, AD complies with all criteria of the first set and with two criteria of the second set; therefore, it is considered eligible to be listed as laid down in Article 5 of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about AD disease (Tables 3, 4, 5, 6 and 7). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was ten. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 3: Outcome of the expert judgement related to the criteria of section 1 of Annex IV (category A of Article 9) for Aujeszky's disease

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	N
2.1	The disease is highly transmissible	N
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	NC
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	NC
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 4: Outcome of the expert judgement related to the criteria of section 2 of Annex IV (category B of Article 9) for Aujeszky's disease

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	Y
2.1	The disease is moderately to highly transmissible	Y
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	N
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	NC
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	NC
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 5: Outcome of the expert judgement related to the criteria of section 3 of Annex IV (category C of Article 9) for Aujeszky's disease

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is present in the whole OR part of the Union territory with an endemic character	Y
2.1	The disease is moderately to highly transmissible	Y
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	N
At least one criterion to be met by the disease: In addition to the criteria set out above at point 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	NC
5(a)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	NC
5(d)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 6: Outcome of the expert judgement related to the criteria of section 4 of Annex IV (category D of Article 9) for Aujeszky's disease

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of section 1, 2, 3 or 5 of Annex IV of AHL		Y

Colour code: green = consensus (Yes/No).

Table 7: Outcome of the expert judgement related to the criteria of section 5 of Annex IV (category E of Article 9) for Aujeszky's disease

Diseases in category E need to fulfil criteria of section 1, 2 or 3 of Annex IV of AHL and/or the following:		Final outcome
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	Y

Colour code: green = consensus (Yes/No).

3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 8, 9 and 10). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

Table 8: Outcome of the expert judgement related to criterion 4 of Article 9

Question*		Final outcome	Response		
			Y (%)	N (%)	na (%)
4 (cat.A,B)	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	NC	64	18	0
4 (cat.C)	The disease has a significant impact on the economy of the Union, mainly related to its direct impact on certain types of animal production systems	NC	18		

NC: non-consensus; Number of judges: 11.

*: At the time of the collective judgement the assessment of the current impact (CI) considering the control measures in place was considered.

Reasoning supporting the judgement

Supporting Yes for 4 (cat.A,B):

- Currently, there is an economic impact in more than two countries and this can be considered significant for the Union.
- All types of pig production and even other animal species of significant importance (e.g. cattle) can be potentially affected, if the disease would be introduced.

Supporting Yes for 4 (cat.C):

- There may be high mortality in piglets.
- In countries where the disease is still present, in breeding and finishing herds, the herd seroprevalence is generally high and can reach 60–100%.

Supporting No for 4 (cat.A,B,C):

- Currently, countries with a pig industry of relevance to the EU economy have AD eradicated. Countries with endemic ADV have a pig industry of lesser importance to the economy of the Union, and in the presence of vaccination currently does not even have a reported impact on the economy of the individual MS so therefore it cannot have an impact on the economy of the Union as a whole. Furthermore, the limited studies on the impact of ADV on production are mainly related to the situation in the 1970s/1980s when the pig industry was different than nowadays.

Table 9: Outcome of the expert judgement related to criterion 5(b) of Article 9

Question*		Final outcome	Response		
			Y (%)	N (%)	na (%)
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC	82	18	0

NC: non-consensus; Number of judges: 10.

*: At the time of the collective judgement the assessment of the current impact considering the control measures in place was considered.

Reasoning supporting the judgement

Supporting Yes:

- In a population with endemic ADV (including wild pig or wild boar populations), the clinical manifestation of the disease is only seen if naïve animals are exposed and the nature of the manifestation then depends on a multiplicity of factors. In addition, the data reported on seroprevalence does not seem to indicate that a large number of wild boar would be affected with severe clinical signs. Therefore, naïve wildlife can have clinical symptoms and piglets from naïve sows high mortality but little or no evidence is available.
- Severe signs such as encephalitis and itching (mad itch) in affected animals impact animal welfare.

Supporting No:

- Currently, many MSs have an infrequent occurrence.
- It is not known if a large number of animals could potentially be affected.

Table 10: Outcome of the expert judgement related to criterion 5(c) of Article 9

Question*	Final outcome	Response		
		Y (%)	N (%)	na (%)
5(c) The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	NC	40	60	0

NC: non-consensus; Number of judges: 10.

*: At the time of the collective judgement the assessment of the current impact considering the control measures in place was considered.

Reasoning supporting the judgement

Supporting Yes:

- Endangered carnivores (e.g. bear, lynx) can potentially be affected, although not currently. Few deaths in already rare animal species may have an impact on the biodiversity.

Supporting No:

- The disease does not appear currently to threaten the survival of largely abundant species such as wild boar or even endangered species at a level leading to a significant impact.

3.3.2. Outcome of the assessment of criteria in Annex IV for Aujeszky's disease for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 3–7. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'.

A description of the outcome of the assessment of criteria in Annex IV for AD for the purpose of categorisation as in Article 9 of the AHL is presented in Table 11.

Table 11: Outcome of the assessment of criteria in Annex IV for Aujeszky's disease for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1 set of criteria					2 set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	N	N	Y	Y	Y	N	NC	N	NC	NC	N
B	Y	Y	Y	Y	N	N	NC	N	NC	NC	N
C	Y	Y	Y	Y	N	N	NC	N	NC	NC	N
D						Y					
E						Y					

According to the assessment here performed, AD complies with the following criteria of the sections 1–5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

- 1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment AD complies with criteria 2.2, 2.3 and 2.4 but not with 1 and 2.1. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and AD does not comply with criteria 3, 5a and 5d, and this assessment is inconclusive on compliance with criteria 4, 5b and 5c.
- 2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment AD complies with criteria 1, 2.1, 2.2 and 2.3 but not with 2.4 because the disease is associated with high mortality instead of low mortality. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and AD does not comply with criteria 3, 5a and 5d and this assessment is inconclusive on compliance with criteria 4, 5b and 5c.
- 3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment AD complies with criteria 1, 2.1, 2.2 and 2.3 but not with 2.4 because the disease is associated with high mortality instead of low mortality. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and AD does not comply with criteria 3, 5a and 5d and this assessment is inconclusive on compliance with criteria 4, 5b and 5c.
- 4) To be assigned to category D, a disease needs to comply with criteria of section 1, 2, 3 or 5 of Annex IV of the AHL and with the specific criterion D of section 4, which AD complies with.
- 5) To be assigned to category E, a disease needs to comply with criteria of section 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5, which AD complies with.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about AD. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

- a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
- b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.³ According to the mapping, as presented in table 5, section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for Aujeszky's disease according to the criteria of Article 8(3) of the AHL are as displayed in Table 12.

Table 12: Main animal species to be listed for Aujeszky's disease according to criteria of Article 8 (source: data reported in Section 3.1.1.1)

	Order	Family	Genus/species
Susceptible*	Artiodactyla	Suidae	All
Reservoir	Artiodactyla	Suidae	<i>Sus scrofa</i>
Vectors	None		

*: Nearly all other mammals can be infected as dead-end hosts, except higher primates.

4. Conclusions

TOR 1: for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;

- According to the assessment here performed, AD complies with all criteria of the first set and with two criteria of the second set and therefore can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

TOR 2a: for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;

- According to the assessment here performed, AD meets the criteria as in sections 4 and 5 of Annex IV of the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1) of the AHL.

TOR 2b: for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.

- According to the assessment here performed, the animal species that can be considered to be listed for AD according to Article 8(3) of the AHL are, as susceptible species, the species belonging to the family of Suidae and nearly all other mammals as dead end hosts (except higher primates), and *Sus scrofa* as reservoir species, as reported in Table 12 in Section 3.4 of the present document.

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³ A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors, the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

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Abbreviations

AD	Aujeszky's disease
ADV	Aujeszky's disease virus
AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
ELISA	enzyme-linked immunosorbent assay
ICBA	Individual and Collective Behavioural Aggregation
MDG	mean daily growth
MRDG	mean relative daily weight gain
MS	Member State
PCR	polymerase chain reaction

SPF	specific pathogen-free
TCID ₅₀	50% Tissue Culture Infective Dose
ToR	Terms of Reference
VN	virus neutralisation